510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned	510(k) number is:	
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1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888 Fax: +86 755 2658 2680

Contact Person:

Tan Chuanbin Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: May 26, 2009

2. <u>Device Name</u>: DC-3/DC-3T Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

The subject device is substantially equivalent in its technologies and functionality to the original DC-3/DC-3T Diagnostic Ultrasound System that is already cleared under premarket notification number K083505, and the other predicate devices are listed below: Mindray M5 (K080640), Mindray DC-6 (K072164), GE Voluson 730 (K041688).

4. Device Description:

The DC-3/DC-3T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of gynecology, obstetrics, abdominal, pediatric, small parts (breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac transvaginal, transrectal, peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

6. Safety Considerations:

The DC-3/DC-3T Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard: 2004. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DC-3/DC-3T Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.



JUL - 9 2009

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K091941

Trade/Device Name: DC-3/DC-3T Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: June 24, 2009 Received: June 30, 2009

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-3/DC-3T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5A 6CV1 7L4A 7L6 10L4 6C2 6LE7 6LB7 3C1

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours

Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System	×		Transducer	
Model:		DC-3/DC-3T		
510(k) Number(s)				

Clinical Application			-,		Mode of (Operation		
Ophthalmic	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
	↓	<u> </u>		l				· · · · · · ·
Fetal	P	P	P		Р	Р	P	Note I 7 2 4
Abdominal	P	P	P	P	P	Р	P	Note 1, 2, 3, 4,
Intraoperative (specify)*	P	P	P		Р	P	<u>-</u> -	Note 1, 2, 3, 4,5
Intraoperative (Neuro)		1	<u> </u>				- F	Note 2, 3, 4
Laparoscopic]						
Pediatric	P	P	P	P	P	P		
Small organ(specify)**	P	P	P				P	Note 1, 2, 3, 4,5
Neonatal Cephalic	. P	P	P	Р	P	Р	P	Note 2, 3, 4
Adult Cephalic	P	P	P	- F	Р.	P	P	Note 1, 2, 3, 4
Frans-rectal	P	P	P		Р .	P	P	Note 1,2, 3
Frans-vaginal	- P	P	P		P	P	P	Note 2, 3, 4
rans-urethral	 	-	F +		Р	P	P	Note 2, 3
rans-esoph.(non-Card.)		 						
Musculo-skeletal Conventional	P	Р	P		P	P	P	Note 2 2 4
lusculo-skeletal Superficial	P	P	P		- P			Note 2, 3, 4
ntravascular						P	_ P	Note 2, 3, 4
ardiac Adult	P	Р	P	P	P			<u> </u>
ardiac Pediatric	Р	P	P	- <u>P</u>		P	P	Note 1, 2, 3
travascular (Cardiac)				- P	P	P	P	Note 1, 2, 3
rans-esoph.(Cardiac)		 	 -		$-\!\!\!-\!\!\!\!+$			
tra-Cardiac			- +	 -	- 			
ripheral Vascular	P	P			 +-			
ther (specify)***	P	P	P		P P	P	P -	Note 2, 3, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW + Color + B, Power + PW + B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

Note 5: 4D

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

System				Transd	ucer	×		
Model:			3C5A				•	-
510(k) Number(s)					-			
					-			
					Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color	Amplitude	Combined	Ī., ,
Ophthalmic		 -			Doppier	Doppler	(specify)	Other (specif
Fetal	 -	-	 		ļ		·	
Abdominal	P	P	Р	ļ	P	P	P	Note 1, 2, 3
Intraoperative (specify)*	P	P	P	ļ	P	Р	. P	Note 1, 2, 3
Intraoperative (Neuro)	-	 	 		<u></u>			
Laparoscopic		├						
Pediatric	+	 _ _						
Small organ(specify)**	P	P	P		P	Р	P	Note 1, 2, 3
Neonatal Cephalic	_	 	ļ					
Adult Cephalic		├						·
Trans-rectal	 				· ·			
Trans-vaginal	+	 						
Trans-urethral	1							<u>. </u>
Trans-esoph (non-Card.)	+							<u> </u>
Musculo-skeletal Conventional								
Musculo-skeletal Superficial	+							
Intravascular	1-1							
Cardiac Adult	╅							
Cardiac Pediatric	+ -							
Intravascular (Cardiac)	+						_	
Frans-esoph (Cardiac)	╂╾╼┤							
Intra-Cardiac	+ 1]	
	 							
Peripheral Vascular	P	_ P	P		P	Р	P	Note 1, 2, 3
Other (specify)***	<u> </u>	P	P		_ P	P	P	Note 1, 2, 3
N=new indication; P=previously c	leared by	FDA;	E≂added	under A	ppendix E			
Additional comments:Combined n	nodes: B	⊦M, PV	/+B, Col	or + B, I	ower + B	PW +Color	⊦B, Power +	PW +B.
*Intraoperative include	s abdomi	nal, the	racic, an	d vascul	ar etc.			
**Small organ-breast, t		estes, e	tc.					
***Other use includes l								
Note 1: Tissue Harmon	ic Imagin	ig. The	feature (loes not	use contra	st agents.		
Note 2: Smart3D								
Note 3: iScape								
Note 4: iBeam								
······		_						·

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

Model:		_		Transd	ucer	Х		
Ploaci.			6CV1			×	-	
510(k) Number(s)			_		••			
			-		_			
				· 	Mode of	Operation		
Clinical Application	В	M	Dur	- · · ·	Color	Amplitude	Combined	Т
Yeld 2		IVI	PWD	CWD	Doppler	Doppler	(specify)	Other (speci
Ophthalmic .							<u> </u>	·
etal	P	P	P		P	Р	P	Note 2, 3
Abdominal		ļ						11000 2, 3
ntraoperative (specify)*						-		
ntraoperative (Neuro)		<u> </u>						
арагоѕсоріс								
ediatric								
mall organ(specify)**								
eonatal Cephalic								
dult Cephalic								
rans-rectal	P	Р	Р		P	P		
ans-vaginal	Р	Р	Р		P	Р -	P	Note 2, 3
ans-urethral							- -	Note 2, 3
ans-esoph.(non-Card.)								
usculo-skeletal Conventional					 -	 		
usculo-skeletal Superficial	7 -			┈╢				
ravascular				-+				
rdiac Adult								
rdiac Pediatric	1		·					
ravascular (Cardiac)								
ins-esoph.(Cardiac)	1-1							
ra-Cardiac	+ -				-+			
ipheral Vascular	 	-+			 -			
er (specify)***	P		P		_			
new indication; P=previously o			P		P	Р	P	Note 2, 3
litional comments Combined	nodes: Bu	FUA; J	=added	under A	ppendix E			
litional comments:Combined a	s abdam	nal Aba	+B, Colo	r + B, P	ower + B, I	PW +Color+	B, Power +	PW +B.
*Intraoperative include **Small organ-breast, (thimpid t	nai, thoi	acic, and	vascula	r etc.	·		
***Other use includes	Ligitora, re	stes, etc	<u>. </u>					
Note 1: Tissue Harman	Drology.	ford .						
Note 1: Tissue Harmon Note 2: Smart3D	ic imagin	g. The f	eature do	es not u	se contrast	agents.		
Note 3: iScape		·						
Note 4: iBeam								
Trote 4. IBcam				:				

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510(k) Number .

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System				Transdu	car	V		
Model:		_	7L4A	r ranscu	CCI	<u>×</u>	_	
510(k) Number(s)			/LHA		_			
					_		•	
CI.					Mode of (Ineration		
Clinical Application			Ţ	T	Color		T	
	В	M.	PWD	CWD	Doppler	Amplitude Doppler		Other (specif
Ophthalmic			 		- sppier	Doppiei	(specify)	
Fetal					 			
Abdominal	₽	P	P		P	р	 _	·
Intraoperative (specify)*		T	 			<u> </u>	P	Note 2, 3, 4
Intraoperative (Neuro)			 		 			
Laparoscopic			 -					
Pediatric	P	P	P		P			
Small organ(specify)**	p .	P	P			P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic		 	 ' 	·	P	P	P	Note 2, 3, 4
Frans-rectal	 		 					
Frans-vaginal								
Frans-urethral		 	 -					
Trans-esoph.(non-Card.)	 		 					
Ausculo-skeletal Conventional	P	P	P					
Ausculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
ntravascular	<u> </u>				P	P	Р	Note 2, 3, 4
ardiac Adult								
Cardiac Pediatric								
ntravascular (Cardiac)].				
rans-esoph.(Cardiac)	 					,		
ntra-Cardiac			-					
eripheral Vascular	P							
ther (specify)***	 -	P	P		P	P	P	Note 2, 3, 4
=new indication; P=previously cl	eared by	FDA; E=	added und	er Append	lix E			
dditional comments:Combined m	odes: H+	M, PW+	3, Color +	B, Power	+ B, PW +	Color+ B, P	ower + PW +	B.
- Franco mondo	audoniiii)	iai, inorac	ic, and var	scular etc.				
**Small organ-breast, th	yroid, tes	stes, etc.						
***Other use includes U	rology.							
Note 1: Tissue Harmonie	Imaging	. The fea	fire does r	of use po				<u> </u>
Note 2: Smart3D	- 0 -	,	10003	ioi use coi	ntrast agen	ts.		
Note 3: iScape				· · · · ·				
Note 4: iBeam								
		_						

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Radiological Devices

510(k) Number

D	iagnosi	tic Ultı	rasound	I Indica	ations fo	r Use Fo	rm	
System				Transdu	сег	×		
Model:			7L6		~~ 1	^	_	
510(k) Number(s)			720		_			
								
Clinical Application					Mode of (Operation		
- ppoution	В	М	PWD	CWD	Color	Amplitude		Other (specify
Ophthalmic		† 		-	Doppler	Doppler	(specify)	.Other (specify
Fetal			 -					
Abdominal	P	P	P					
Intraoperative (specify)*	 	 	 		P	P	P	Note 2, 3, 4
Intraoperative (Neuro)	 		 					
Laparoscopic	 	 	 		 			
Pediatric	Р.	P	P P					
Small organ(specify)**	P	P	P		P P	Р	P	Note 2, 3, 4
Neonatal Cephalic		P	P		P	P	P	Note 2, 3, 4
Adult Cephalic	 		^P		P	Р	P	Note 2, 3, 4
Trans-rectal	1	<u>-</u> -	 	-, -				
Trans-vaginal	†		 					
Trans-urethral	 							
Trans-esoph (non-Card.)	 							
Musculo-skeletal Conventional	P		P					
Musculo-skeletal Superficial	P	- <u>-</u>	P		_ P	P	P	Note 2, 3, 4
Intravascular	 				P	P	Р	Note 2, 3, 4
Cardiac Adult	 							
Cardiac Pediatric		 						
ntravascular (Cardiac)		 						
rans-esoph.(Cardiac)								
ntra-Cardiac		 -						
eripheral Vascular	P	P						
other (specify)***		F	P		P	P	P	Note 2, 3, 4
I=new indication; P=previously cl	eared by I	EDA. E						
dditional comments: Combined m	odec D: I	DA; E=	added und	ег Аррепо	lix E			
dditional comments:Combined m	abdomina	al. thorac	ic and we	B, Power	+ B, PW +	Color+ B, P	ower + PW +	В.
**Small organ-breast, th	vroid, tes	tes, etc	io, and va	cuiar eic.				
***Other use includes L	rology.	, 0.0.					<u></u>	
Note 1: Tissue Harmoni	Imaging	. The fea	ture does r	of use co	ntraát o			
Note 2. Sman3D	<u></u> _			- uac co	nuasi agen	LS.		
Note 3: iScape		· <u>·</u>				<u> </u>		
Note 4: iReam								

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510(k) Number _

						_		
Clinical Application			·		Mode of (Operation		
	В	М	PWD	CWD	Color	Amplitude	Combined	
Ophthalmic		+			Doppler	Doppler	(specify)	Other (specif
Fetal		┼	 					
Abdominal	P	P	P		P			
Intraoperative (specify)*			 		- P	P	P	Note 2, 3, 4
Intraoperative (Neuro)			1		:			
Laparoscopic Pediatric								
	P	P	Р		P	P		, -
Small organ(specify)** Veonatal Cephalic	P	Р	P		P	P	P	Note 2, 3, 4
Adult Cephalic	P P	Р	Р		P	P	P	Note 2, 3, 4
Frans-rectal		[Note 2, 3, 4
rans-vaginal							 -	
rans-urethral	 						}	-
rans-esoph.(non-Card.)	+							
Ausculo-skeletal Conventional	P P							
Iusculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
ntravascular	1	- P -	P		P	P	P	Note 2, 3, 4
ardiac Adult	 							, , ,
ardiac Pediatric	 							
travascular (Cardiac)	 -{		 -					
rans-esoph.(Cardiac)								
tra-Cardiac	1			 -				
ripheral Vascular	P	P	P					
her (specify)***				 -	_ P	P	P	Note 2, 3, 4
new indication; P=previously cl	eared by F	DA: E=a	dded under	4				
ditional comments:Combined m *Intraoperative includes	odes: B+N	1. PW+B	Color + B	Appendi	X E			
*Intraoperative includes	abdomina	l thoraci	C and ween	nlan -t-	B, PW +C	Color+ B, Pov	ver + PW +B	
**Small organ-breast, th	vroid test	ec etc	o, and vasc	utar etc.				-
***Other use includes U	Irology	C3, CIC.						
Note 1: Tiesus Harmoni	Tology.	-						
Note 1: Tissue Harmonic Note 2: Smart3D	maging.	The feat	are does no	t use cont	rast agents			
Trote 2, Sinarisi								
Note 3: iScape								 _
Note 4: iBeam								

System				Transduc	er	×		
Model:		_	6C2				•	
510(k) Number(s)		····			-			
			<u> </u>		_			
					Mode of (Ineration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	┪	 	-				(4/2011)	
Fetal	+							
Abdominal	P	P	P	 -	<u>-</u>			
Intraoperative (specify)*	+ -	+	 '		Р	P	Р	Note 2, 3
Intraoperative (Neuro)	1		 		 			
Laparoscopic	+	 			ļ			
Pediatric	P	P	P	· ·	·			
Small organ(specify)**	 	 	 '- 		Р	Р	P	Note 2, 3
Neonatal Cephalic	P	P	P		P			
Adult Cephalic	P	P	P	<u> </u>	P	P	P	Note 2, 3
Trans-rectal	+	 	 - 			P	P	Note 2, 3
Trans-vaginal	 	 	1					
Trans-urethra	 	 -	 		-			
Trans-esoph.(non-Card.)	†							<u> </u>
Musculo-skeletal Conventional	1							
Musculo-skeletal Superficial	 		1 -					
Intravascular	 				 			
Cardiac Adult	P	P	P		· P			
Cardiac Pediatric	P	P	P			- P	P	Note 2, 3
Intravascular (Cardiac)	1	<u> </u>	-	- · - 		P	P	Note 2, 3
Trans-esoph.(Cardiae)								
Intra-Cardiac	1 -		 				 -	
Peripheral Vascular	 							
Other (specify)***	P	P	Р		P			
N=new indication; P=previously c	leared by I					P	P	Note 2, 3
Additional comments:Combined or	nodes B+i	M PW+I	R Color+	В Волия	A D. Day	01.00		
*Intraoperative include	s abdomin	al thorn	ric and me	ouler etc	TD, PW T	C0101+ B, P0	Wer + PW +E	ł.
**Small organ-breast, t	hyroid, tes	tes etc	oro, and vas	cuiai cic.	·		 	
***Other use includes I			-			_		
Note 1: Tissue Harmon		. The fee	atitre does r	ot use on	ntract acco	4-		
Note 2: Smart3D		. 1110 101	itare does i	ioi use coi	iitiasi agen	is.		
Note 3: iScape			<u> </u>				· · · · · · · · · · · · · · · · · · ·	
Note 4: iBeam					<u>·</u>		·	
						······		
	V	$\left(\frac{1}{2} \right)$				······································		

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Radiological Devices 510(k) Number ____

PW D P P	CWD	P P	de of Operati	P P	Other (specify Note 2, 3, 4
P	CWD	Color Doppler P	Amplitude Doppler P	Combined (specify)	Note 2, 3, 4
P	CWD	Color Doppler P	Amplitude Doppler P	Combined (specify)	Note 2, 3, 4
P	CWD	Color Doppler P	Amplitude Doppler P	Combined (specify)	Note 2, 3, 4
P	CWD	P	P	(specify)	Note 2, 3, 4
			P	P	
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		P	P	P	Note 2, 3, 4
P		Р	P	P	Note 2, 3, 4
<u></u>		-	P	P	Note 2, 3, 4
		-			
+				ŀ	
			,		
├-					
		- 			
-					
<u> </u>		Р	P	P	Note2, 3, 4
-add	ed unde	Appendia	кE		
+B, C	olor + E	Power +	B, PW +Col	or+ B, Power	+ PW +B.
гасіс, а	and vaso	cular etc.			
3.		<u> </u>	·		
cature	e does ne	ot use cont	rast agents.		
	·				
,	/+B, C racic, c.	/+B, Color + E racic, and vaso c.	/+B, Color + B, Power + racic, and vascular etc. c.	/+B, Color + B, Power + B, PW +Col racic, and vascular etc.	/+B, Color + B, Power + B, PW +Color+ B, Power racic, and vascular etc.

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

O Jacon				Transdi	ıcer	×		
Model:			6LB7				•	
510(k) Number(s)					.			
					_			
Clinical A 15					Mode	of Operation		
Clinical Application	В	М	PW	CWD	Color	Amplitude	Combined	Γ
Ophthalmic	-		D		Doppler	Doppler	(specify)	Other (specify
Fetal		+-	-	L	<u> </u>			
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)		 	-					
Laparoscopic								
Pediatric	- -	-	-					
Small organ(specify)**		╂	-					
Neonatal Cephalic	-	 	11					
Adult Cephalic		 	 					
Trans-rectal		 						
Trans-vaginal	P	P	P		P	P	P	Note 2, 3, 4
Trans-urethral		╂						
Trans-esoph.(non-Card.)		┨						
Musculo-skeletal Conventional	+-	-	 					
Musculo-skeletal Superficial	╅╾	 						
Intravascular	 	-						
Cardiac Adult	+		 					
Cardiac Pediatric	+		┝╶┤					
ntravascular (Cardiac)	+		├─┼					
Frans-esoph.(Cardiac)	+	-	-+					
ntra-Cardiac	1							
eripheral Vascular	1-							
Other (specify)***	-		-					
	P	P	P		<u>P</u>	P	P	Note2, 3, 4
l=new indication; P=previously c	leared b	y FDA	E=ad	ded unde	Appendia	c E		
*Intrapperative include	nodes: E	3+M, P	W+B,	Color + I	Power +	B, PW +Col	or+ B, Powe	r + PW +B.
manaperative include	s abdon	ninal, t	horacic,	and vas	cular etc.			
***Other use includes	nyroid,	testes,	etc.					
Note 1. Tiesus Userna	Urology	·				<u> </u>		
Note 1: Tissue Harmon Note 2: Smart3D	ic imagi	ing. Th	e featu	re does n	ot use cont	rast agents.		
Note 3: iScape			· · ·					
Note 4: iBeam								

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Radiological Devices \$\foq (94)\$

Division of Reproductive, Abdominal and

(Division Sign-Off)

Diagn	ostic	Ultr	asou	nd Ind	ication	s for Use	Form	
System				Transdi	ucer	×		
Model:			3C1				-	
510(k) Number(s)					-			
	-, -							
Clinical Application	<u> </u>				Mode	of Operation	1	
	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify
Ophthalmic						- '-	(opoonly)	·
Fetal .	P	P	P		P	Р	P	Note 1 2 2
Abdominal	P	. P	Р		P	P	Р -	Note 1, 2, 3
Intraoperative (specify)*		1				<u> </u>		Note 1, 2, 3
Intraoperative (Neuro)		1				·		
Laparoscopic	\top	1	1-					
Pediatric	P	P	P		P	P		N
Small organ(specify)**		-					P	Note 1, 2, 3
Neonatal Cephalic	1	1						
Adult Cephalic	_	 	1 1					
Trans-rectal	1	-			,			
Trans-vaginal	1-	† –			 			
Trans-urethral	†		1					
Trans-esoph.(non-Card.)	† –	<u> </u>			 			
Musculo-skeletal Conventional	 	<u> </u>						
Musculo-skeletal Superficial								
Intravascular	1	_	-					
Cardiac Adult	P	P	P	-				
Cardiac Pediatric	P	P	P		P	P P	P	Note 1, 2, 3
ntravascular (Cardiac)			-			P	P	Note 1, 2, 3
Frans-esoph.(Cardiac)					 -}-			<u> </u>
ntra-Cardiac	-			-+	 }			·
eripheral Vascular	 		-+	- 				
other (specify)***								
l-new indication; P-previously c	leared I	w FD						
dditional comments:Combined m	nodes: 1	3+M I	T, E-ac	Cal	er Append	ix E	<u> </u>	
dditional comments:Combined m	s abdor	ninal e	horosi	Color +	B, Power	+ B, PW +C	olor+ B, Pow	/er + PW +B.
**Small organ-breast, ti	hyroid	tertan	noracio	, and vas	scular etc.		· .	
***Other use includes I			eic.					
Note 1: Tissue Harmoni			o foot			·	<u> </u>	
Note 2: Smart3D	- mag	mg. II	ic ican	HE HOES I	not use cor	itrast agents.		
Note 3: iScape				· · · · · · · · · · · · · · · · · · ·				
Note 4: iBeam								
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(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number _

	20110	ÇIH.	43VU1	ia IIIU	acations	s for Use	Form			
System		_		Transdu	rcer	×				
Model:			2P2		_		-			
510(k) Number(s)					-					
							_			
Clinical Application	Mode of Operation									
- Application	В	М	PW	CWD	Color	Amplitude	Combined	04 / 10		
Ophthalmic		- 	₽ D		Doppler	Doppler	(specify)	Other (specify)		
Fetal	┪—	+	╂							
Abdominal	P	┥ <u>、</u>	 -					-		
Intraoperative (specify)*	+-	P	P	P	P	.Р	P	Note 1, 2		
Intraoperative (Neuro)	-		-							
Laparoscopic		┼─								
Pediatric	P	P								
Small organ(specify)**	 	-	P	P	P	P	P	Note 1, 2		
Neonatal Cephalic	P	P	P							
Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2		
Frans-rectal	┼∸╌	-		- -	- P	P	P	Note 1, 2		
Frans-vaginal	 	<u> </u>								
Frans-urethral	 	-								
Trans-esoph (non-Card.)	-	-	-							
Musculo-skeletal Conventional	 									
Ausculo-skeletal Superficial	 		\dashv	 						
ntravascular			\dashv							
Cardiac Adult	P	P	P	P	- i					
Cardiac Pediatric	P	P	P	- 	P	P	P	Note 1, 2		
ntravascular (Cardiac)			∸┼	 -	- <u>r</u>	P	P	Note 1, 2		
rans-esoph.(Cardiac)										
tra-Cardiac										
eripheral Vascular	-		-+	+		 -				
ther (specify)***			\dashv							
=new indication; P=previously cl	eared h	v FD4	· F=ad	ldad sm 4						
dditional comments:Combined m	odes: F	3+M P	W+B	Color d	r Appendi	x E				
*Intraoperative includes	abdon	ninal t	horacio	and year	o, rower a	B, PW +Co	olor+ B, Pow	er + PW +B.		
, **Small organ-breast, tl	vroid.	testes.	etc	, and yas	cular etc.					
***Other use includes I										
Note 1: Tissue Harmoni			e featu	re does r	Of use oc-	troot o				
Note 2: Smart3D					0. 000 0011	uasi agents.	<u> </u>			
Note 3: iScape				<u>·</u>						
Note 4; iBeam										
<i>(</i> 5)										

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

Ι	Diagno	stic U	ltrasoui	nd Indi	cations	for Use I	Form				
System				Transduc	er	×					
Model:		-	7L5				•				
510(k) Number(s)	•			•	-						
					=						
	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic		3.5		-							
Fetal								,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Abdominal	P	P	P		P	P	Р	Note 2, 3, 4			
Intraoperative (specify)*											
Intraoperative (Neuro)											
Laparoscopic						****	-				
Pediatric	P	P	P		P	P	P	Note 2, 3, 4			
Small organ(specify)**	Р	P	P		Р	P	P	Note 2, 3, 4			
Neonatal Cephalic	Р	P	· P	<u> </u>	Р	Р	P	Note 2, 3, 4			
Adult Cephalic						-		· · · · · ·			
Trans-rectal					·						
Trans-vaginal											
Trans-urethral				1	,						
Frans-esoph.(non-Card.)											
Musculo-skeletal Conventional	P	P	Р		Р.	Р	P	Note 2, 3, 4			
Musculo-skeletal Superficial	P	P	P		Р	P	P	Note 2, 3, 4			
Intravascular			1								
Cardiac Adult											
Cardiac Pediatric			1	ļ							
Intravascular (Cardiac)		1.									
Frans-esoph.(Cardiac)											
Intra-Cardiac			1					······································			
Peripheral Vascular	P	P	P		Р	P	P	Note 2, 3, 4			
Other (specify)***				·							
N=new indication; P=previo	ously cle	ared by F	DA; E=ad	lded unde	Appendix	Е					
Additional comments: Comb							or+ B, Power	+ PW +B.			
*Intraoperative i											
**Small organ-b											
***Other use inc	ludes U	rology.	-:	¢		-					
Note 1: Tissue H			. The fean	ire does n	ot use cont	rast agents.					
Note 2: Smart3D		_	······································		•						
Note 3: iScape							· · · · · · · · · · · · · · · · · · ·				
Note 4: iBeam	$\overline{}$			· ·			··· <u>·</u>				
	$\overline{}$				·						

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Radiological Devices

510(k) Number __

System				Transdu	er	×		
Model:			7LT4		-01		-	
510(k) Number(s)					-			
	-				_			
	T				Mode of (Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined	Other (specify)
Ophthalmic					Doppier	Doppler	(specify)	
Fetal			†		 			
Abdominal	P	P	Р		P	P	P	
Intraoperative (specify)*	Р	Р	P		P	P		Note 2, 3, 4
Intraoperative (Neuro)				'	·		P	Note 2, 3, 4
Laparoscopic					-			
Pediatric	P	P	P		P	P	 	
Small organ(specify)**	P	P	P		P		P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		- <u>г</u>	P 72	- P	Note 2, 3, 4
Adult Cephalic		 ` ` 	 		r	P	P	Note 2, 3, 4
Frans-rectal						 -		
Frans-vaginal	 	 						
Frans-urethral	 	 	 					
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P		
Ausculo-skeletal							Р	Note 2, 3, 4
uperficial	P	P	Р		P	P	Р	Note 2, 3, 4
ntravascular							 -	
ardiac Adult								
ardiac Pediatric								
ntravascular (Cardiac)								
rans-esoph.(Cardiac)								
tra-Cardiac	, , , , , ,				 +	- -		
eripheral Vascular	P	P	P		P	P	<u> </u>	
ther (specify)***				- +				Note 2, 3, 4
=new indication; P=previo	usly clea	red by FI	OA: E≔ado	led under	Annandia	<u>_</u>		
dditional comments:Comb	ined mod	les: B+M	. PW+B (Color + R	Power + I	E DW LOST		
*Intraoperative in	ncludes a	bdominal	thoracie	and vaces	lor etc	5, r w +Colo	r+ B, Power -	+ PW +B.
**Small organ-b	reast, thy	roid, teste	s etc	and vasce	itar etc.	 		
***Other use inc			0, 010.		·	-		·
Note 1: Tissue H			The factor	o dono				
Note 2: Smart3D		inidents.	THE PEARLE	e does no	use contra	ast agents.		
Note 3: iScape			-	<u> </u>				<u> </u>
Note 4: Beam								
·	/							

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

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System		_		Transd	исег	×					
Model:		- 1	06-2				=				
510(k) Number(s)					•						
					-						
	Mode of Operation										
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specif			
Ophthalmic					1		(specify)				
Fetal	N	N	N		N	N	N .	Note I, 2, 3,			
Abdominal	N	N	N		N	N	N	Note 1, 2, 3,			
Intraoperative (specify)*		Ī .						14010 1, 2, 3,			
Intraoperative (Neuro)	1	<u> </u>		_							
Laparoscopic						_					
Pediatric	N	N	N		N	N	. N	Note I 2 2			
Small organ(specify)**		l —					- 41	Note 1, 2, 3,			
Neonatal Cephalic		-									
Adult Cephalic			_				· · · ·				
Trans-rectal	 -	-									
Trans-vaginal	 										
Trans-urethral											
Trans-esoph.(non-Card.)											
Musculo-skeletal Conventional	 							<u> </u>			
Musculo-skeletal Superficial	1										
Intravascular											
Cardiac Adult			-								
Cardiac Pediatric	╅										
Intravascular (Cardiac)	1		\dashv								
Trans-esoph.(Cardiac)	+-i										
Intra-Cardiac	╅				 +						
Peripheral Vascular	 										
Other (specify)***	┼╌┤			-+							
N=new indication; P=previously c	leared by	· EDA ·	<u>_</u>				<u>_</u>				
Additional comments: Combined o	noden: D	LM DU	L-addec	under A	ppendix E						
Additional comments:Combined n *Intraoperative include	e nhdomi	1 4b	+6, 00	or + B,	ower + B	, PW +Color	+ B, Power -	+ PW +B.			
**Small organ-breast, t	huroid to	nat, usc	racic, ar	id vascu	ar etc.						
***Other use includes		csies, ei	.c.		 _						
Note 1: Tissue Harmon		o The	Factor								
Note 2: Smart3D	ic magn	ig. The	reature o	oes not	use contra	st agents.	· ·	<u> </u>			
Note 3: iScape											
Note 4: iBeam											
Note 5: 4D											
1100, 3, 41	1			<u> </u>	 ;		<u> </u>				
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ri ' /	/										

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____